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REVIEW AND PERSPECTIVES

Public–private relationships in biobanking: a still underestimated key component of open innovation

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Abstract
Access to human bioresources is essential to the understanding of human diseases and to the discovery of new biomarkers aimed at improving the diagnosis, prognosis, and the predictive response of patients to treatments. The use of biospecimens is strictly controlled by ethical assessment, which complies with the laws of the country. These laws regulate the partnerships between the biobanks and industrial actors. However, private–public partnerships (PPP) can be limiting for several reasons, which can hamper the discovery of new biological tests and new active molecules targeted to human diseases. The bottlenecks and roadblocks in establishing these partnerships include: poor organization of the biobank in setting up PPP, evaluation of the cost of human samples, the absence of experience on the public side in setting up contracts with industry, and the fact that public and private partners may not share the same objectives. However, it is critical, in particular for academic biobanks, to establish strong PPP to accelerate translational research for the benefits of patients, and to allow the sustainability of the biobank. The purpose of this review is to discuss the main bottlenecks and roadblocks that can hamper the establishment of PPP based on solid and trusting relationships.

Keywords Biobank · Research · Public–private partnerships · Bottlenecks · Contracts · Private company · Indicators

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Introduction

During the last decade, the research and development (R&D) of the pharmaceutical industry has experienced a shift in the paradigm from an internally controlled and closed model toward an external flexible and open developmental model. Biobanks are actively involved in clinical and translational research projects aiming at discovering new biomarkers and targets for innovative therapy [1–3]. The onset of targeted therapies and personalized medicine has considerably boosted the requirement of high-quality samples for the analysis of molecular alterations and deregulation of different signalling pathways that are relevant to new therapeutic options [4]. The collection of authenticated biological resources is of strategic importance. It represents a major challenge, since high-throughput technologies in genomics may generate an unlimited number of hits, but their accuracy depends largely on the quality of both human biological samples and related annotations. However, despite a number of initiatives and claims, a few bottlenecks, which exist in public–private partnerships (PPP), remain largely underestimated.

The purpose of this review is to outline the main bottlenecks to the access to biological resources and to discuss possible solutions to facilitate access in the context of PPP.

How to improve PPP in biobanking? (Box 1)

Box 1 Means to potential improvement in public–private relationships in biobanking

On the academic side
- Provide assurance/quality procedures according to international guidelines and recommendations (OECD, WHO, …)
- Offer a strong medico-scientific expertise in a specific pathological field(s)
- Establish strict governance for the project's management

On the private side
- Involve the biobank as an "active partner" instead of a "supplier-only"
- Define intellectual property rights related to the project

On both sides
- Design the objectives and outlines of the project
- Establish a contract according to international recommendations
- Define the real cost and contributions on both side

Besides the drawbacks related to weaknesses in professional practices, the major drawbacks usually arise from a lack of knowledge of the priorities of both parties when setting up a partnership based on the use of biospecimens. On the side of bio-industry, these include the accuracy of information related to biological resources, access to clinical data and follow-up of patients, turnaround time after request, financial and regulatory conditions, and the intellectual property rights linked to specimens. From a basic research point of view, human biological samples primarily generate high-throughput data and new hypotheses, regardless of the time, cost effectiveness, and effort, which should be considered together. Academic translational research aspires to transfer knowledge to the bedside and vice versa, but is usually not based on market conditions, cost effectiveness, and timing to reach the goal. It is therefore necessary to refocus the objectives of biobanks, particularly while taking into account the emerging paradigm of "open innovation." In addition, a biobank should provide external partners not only with samples and associated data but also with the knowledge and expertise, which motivate the collection of biological materials. To achieve this goal, a biobank could limit the number of collections of human specimens according to its scientific and medical background. The biobank could integrate and/or have privileged access to top-level technological platforms to analyze specimen derivatives. Consequently, the characteristics of an effective biobank should evolve from those of a "supplier" toward those of an active "partner". Importantly, by sharing the same objectives, key bottlenecks could be revisited by both parties, including the access to information linked to specimens and conditions for running the project. In addition to material transfer agreements dealing with access to biological resources, contracts should include cost and intellectual property rights related to the scientific project. Finally, industry would benefit from a strong and well-established partnership by gaining access to highly precompetitive technology and knowledge linked to diseases.

Biobanks have different interlocutors depending on the nature of the need. Research scientists from the academic or industrial world can ask biobanks to provide human samples, with the aim of looking for new diagnostic, prognostic, and theranostic biomarkers. The majority of biobanks belong to public health care institutions. Even though these biobanks generally collaborate with academic scientists, they can also develop research programs with industrial and private partners. Collaboration of an academic biobank through biospecimen cession to academic scientists has existed for many years and is usually done without major difficulties. In contrast, there is an urgent need to optimize PPP. It is noteworthy that to compensate for this problem, an increased number of private biobanks are currently being set up to meet the needs of industrial partners.

A number of international recommendations to facilitate the use of biological specimens under optimal conditions have been published [5]. These specifications have somewhat clarified the missions and governance of the biobanks, which operate at the interface between research and health care. Thus, biobanks provide strict rules and governing bodies to allow access to the resources, catalogues of specimens, storage facilities, certified processes, quality assurance procedures, and qualified human resources [6, 7]. According to these international recommendations and provided they meet these requirements, all biobanks should be accessible for research projects regardless of whether they come from either academic or industrial parties.

Why do some bottlenecks still exist when developing PPP in biobanking? (Box 2)

Box 2 Possible explanations for existing bottlenecks between public and private partners in biobanking

- Differences in vision and policy
- Differences in business models
- Limited number of expert biobank centers in a specific pathological field(s)
- Heterogeneity in the professional practices of the different biobanks

For years, academic biobanks have worked with physicians and research scientists from academic institutions (universities and hospitals). In the field of cancer, tumor biobanks encompass two missions: (1) A health and sanitary mission dedicated to diagnosis, prognosis, and genomic analyses for the benefit of patients. Thus, in most countries, such as in France, this mission cannot be considered for the aims of research projects but for patient health care only. The interface between the

physician, the pathologist, the biobanker, and the molecular biologist is then obvious; (2) a translational research mission by participating in collaborative programs gathering together academic and/or researchers from various networks. Roughly, for people working in the public sector, a biobank should help to optimize health care and/or to develop an academic research program. For private or industrial partners, the biobank aims to rapidly obtain samples to quickly validate selected and robust biomarkers, to develop a commercial test, or to assess the potential of a chemical entity in winning market shares as a future drug. Thus, the bottlenecks existing between the biobanks and the private partners can result from the fact that the value of a biobank is not seen in the same way by academia and the private sector, and that these two worlds do not share the same objectives when using biospecimens. The main goal of the academics is to publish data in journals with a good impact factor or to be involved in clinical trials that promote the institution. Conversely, one of the main goals of a private company is to enhance its economic efficiency in accordance with the established business plan and the different investments made in developing a new molecule for treatment or for setting up a new biological test. However, whatever the different goals, the private or public partners of a biobank should always keep in mind that the partner who uses products from a human biobank has to assure that the samples they receive are of high quality, respecting international standards and in compliance with ethics and laws. Moreover, these partners have to recognize the fact that the main reason for collecting and using human biological samples is to find better ways of diagnosing and treating human diseases. Finally, they need to realize that the benefit to the user is actually small in comparison with the benefit afforded to future patients [8]. Moreover, one important bottleneck in most European countries is that biobanks are responsible for what is done with the samples and need to know and register the experiments that will be done by the researchers using these samples. So, it is important for a biobank to get information concerning the design and the goal of the experiments made by the private partners. This information should be obtained before a signed Material Transfer Agreement (MTA), which can be a difficult process to setup with industrial partners. Getting a confidential disclosure agreement signed by all partners before making the MTA can also facilitate the efficiency of the turnaround time of the process. Additionally, the MTA should mention that samples (and their derivatives) should either be returned to the biobank or destroyed. In addition, certain industrial partners rely on different private structures that act like "brokers" to get samples from academic biobanks. If a contract is set out with industrial partners through these intermediate private structures, it has to be written into the contract that all samples be sent to the industrial partners without promoting additional private biobanks with these samples. International Standard Organization (ISO) certified and/or accredited private–public laboratories that can do the analyses and provide data for the private partner who asked samples from the biobanks can act as another intermediate between the biobank and the pharmaceutical and diagnostic companies. These core facilities can be located outside or inside the biobanks.

Regardless of the partners (industrial and diagnostic companies, intermediate structures, and technical platforms using and analyzing the samples), it is crucial to provide the well-defined access rules of a biobank to allow external requests to be made. These rules should clearly outline the functioning of each biobank.

Currently, many hospitals and academic structures are setting up biobanks, but there is a lot of heterogeneity in the professional practices and thus, a lot of heterogeneity in the quality of the biological materials themselves. Should we recommend that only a few selected tumor banks be devoted primarily to science, and identify "expert" biobank centers? In a conventional setting, the tumor sample is linked to the patient's medical file, only. Alternatively, the tumor sample is part of a collection that should be made accessible to various partners with a high level of expertise, but under specific conditions.

Why and how does an academic biobank demonstrate that it is a high achieving structure? (Box 3)

Box 3 Main criteria of an attractive biobank for public–private partnerships

- Indicators demonstrating the "good value" of biological samples and clinical associated data
- Certification and/or accreditation of the biobank, according to OECD recommendations
- Strict and transparent governance of the biobank
- In-house expertises and R&D capacity
- Willingness, tools, and capacity to collaborate

An academic biobank has to demonstrate that it can work efficiently with partners by referring to critical indicators [9, 10]. However, how can these different indicators be identified? The criteria for evaluating biobanks are certainly variable and numerous. It is necessary to treat them on a hierarchical basis and to separate them into different broad categories. Moreover, the follow-up of these indicators over time should optimize the running and the international visibility of a biobank [11]. The current high number of biobanks worldwide make this field very competitive, and there is an urgent need of "professionalization" of academic biobanks to set up better, sustained PPPs. Different categories of indicators can be proposed to evaluate biobanks, such as parameters related to activity and assurance quality, those concerning the scientific production of the biobank itself, and miscellaneous points

including, certification and/or accreditation, marketing, and educational programs [9, 10]. Briefly, among all these parameters, some are critical for the functioning of a biobank, such as the quality of updated associated clinical data and the good control of all steps in the pre-analytical phase [12–17]. PPP may be facilitated if the biobank is accredited and/or certified. Although a number of guidelines and recommendations have been published during the last decade, there is currently no international norm for managing biobanks. A number of international laboratory accreditation standards, including the ISO norms 9001, 17025 and 15189 are essential in standardizing laboratory practices. The same holds true for the external quality assessment programs, including those proposed by the United Kingdom National External Quality Assessment Service (UK NEQAS), the European Molecular Genetics Quality Network, and the College of American Pathologists. Importantly, a new norm dedicated to biobanking (AFNOR S96-900) has been recently implemented in France and should be seriously considered in the future by potential private partners and for international extension.

According to a national survey, two models of biobanks coexist, including central platforms that stock biospecimens for further delivery to scientists working outside the biobank ("biorepository structure") and integrated infrastructures that are closely linked to research laboratories by providing appropriate expertise, and may develop their own scientific projects. These two models depend on the policy of the biobank and/or funder's requirements. In addition, depending on their internal organization, some biobanks can operate as a biorepository and also adopt both activities, when required. Moreover, in an additional model, the principal investigator (PI) of the project directly cooperates with both the outside partner and with the biobank for the establishment of a prospective sample collection. In this model, the PI but not the biobanker is the actual steering entity of the project. When a specific expertise is required from the biobank and adds value to the project, a contract should be set up between the different partners, namely PI, biobank, and outside partner.

Is the pricing of samples a main bottleneck?

It is generally thought that the actual cost of the biospecimens provided by an academic biobank is a major bottleneck in PPP. In addition, additional cost may be identified, including those induced by planning, tracking, evaluation, analysis, and ethical and legal issues. Cost recovery is becoming increasingly important with the deployment of national and international networks and consortia, and the access of industry to human samples. Cost assessment strategies for biospecimen retrieval, processing, and appropriate clinical annotation are still under discussion in most academic biobanks, and processes of harmonization are still under debate. The strategies for biospecimen cost evaluation are wide-ranging, as they are closely related to the funding schemes of biobanks. Such heterogeneity certainly hampers access to samples and there is an urgent need to harmonize costs in the near future. It is worthy deciphering the different steps and variables that determine cost assessment of biospecimens and clinical annotation, as is currently done at the European level. Furthermore, it is necessary to reach an agreement on a minimal variable data set that should be included in such an assessment in the future.

To reach these goals, agreements should be made based on a policy to assess the cost of these different steps and variables. For example, the recovery costs for biological resources have been evaluated in France by the French National Cancer Institute (INCa) (www.edu-cancer.fr). However, the cost assessments do not include the cost for the biobank environment and expertise, such as the work of the surgical pathologist and the time of data management. We propose that the cost assessment strategy and thus the pricing of samples can be made at different levels depending on the partner of the biobank (academic research team or industry) and depending on the level of the scientific collaboration with the biobank partner (without or with scientific collaboration with the partner). Ongoing working groups at both the European (http://bbmri.eu/fr) and national levels (e.g., in France http://www.biobanques.eu/) should clarify cost assessments and establish realistic business plans in biobanking.

How to improve the turnaround time after receiving a request for biospecimens?

The long turnaround time (TAT) after a request for biospecimens is undoubtedly one of the major bottlenecks. The time between the request made by the private partner for biological samples and their delivery by the biobank varies considerably from one biobank to another, depending on their organization. The TAT should be discussed at least before setting up and signing the contract, although it depends strongly on the nature of the request. In particular, the TAT can be different for requests of whole frozen specimens, paraffin blocks, nucleic acids, plasma samples, germline DNA, fresh tissues, tissue microarrays, etc. It depends also on the specifications and number of requested samples, on the types of different biological resources required from the same cohort of patients (for example, plasma and tissue), and on the amount and type of associated clinical data.

How to set up a contract and what are the main pitfalls?

A contract must be set up between the biobank and the private partner according to ethical requirements and national laws for use of human samples and clinical

annotation. Such a contract must clearly state the responsibility of each partner and be signed at least by the director of the biobank, the head of the academic institution, and the private partner asking for the biospecimens. It may be necessary to indicate if a project steering committee exists. Different chapters must be addressed in the contract, including the purpose of the contract, the different obligations and duties of the biobank, and the responsible administration of the institution, the obligations regarding the laws, the ethics and the patient privacy and rights, as well as the industrial obligations. The intellectual property must be clearly described, in particular for the exploitation of data provided with the biobank samples, and if a patent will be filed. The possibility or not of obtaining access to data associated with the bioresources (type of pathology, pathological data, clinical data, etc.) has to be mentioned. It is important to describe the nondisclosure commitment, in particular for publication of data generated by analysis of samples. The financial provisions concerning the cost of the samples and the different services offered by the biobank must be clearly indicated. Outside discussion concerning the financial provision can sometimes be a problem since the costs are usually different for the same biological resources from one biobank to another. One pitfall is to write the contract in one language, which is faster and easier than writing it in two languages, e.g., in France in both English and French, which is required by French law when writing a contract with a private partner located outside the country of the biobank. Finally, most of the human samples requested by industry should be "free" of potential infectious agents and this should be clearly stated in the contract. However, it can be difficult for biobanks to determine the potential infectious and hazardous status associated with the samples, in particular the HIV and hepatitis B and C serological status.

How to watch over intellectual property rights?

It is critical in the public sector to break the silence on this point since the biobankers are often poorly informed about the different elements concerning intellectual property (IP). All details concerning IP should be discussed between the partners and outlined in the contract as described above. It is quite obvious that providing samples to a private company for development of a research project does not constitute at all a unique argument for being involved in the potential future commercial exploitation made by the industrial partners. However, we strongly believe that the biobank should be potentially associated in patent rights and/or the copyrights, if the biobank is substantially involved in the design of a project, participates in the scientific discussion, gives advices and expertise, and/or improves the outcome of the project through a core facility associated with the biobank. The area of IP usually includes the copyrights and the patents. The copyright protects ideas and concepts. These include registration forms, instructions, and a variety of publications that are given as examples on the website of the Library of Congress (copyright section: www.copyright.gov). The term of the copyright generally covers the life of the author plus an additional 70 years. If the copyright is a "work for hire," and authorized by an independent contractor, then its term is 95 years from the date of publication or 120 years from the year of its creation, whichever occurs first. Patents usually protect inventions. Patents can be divided into utility patents, design patents, and plant patents. Utility patents protect technological inventions and are arguably the most important class of patents. Examples of inventions protected by utility patents include methods of extracting tissue or cellular products, business methods (software), and pharmaceuticals. The main conditions for receiving a patent are novelty and non-obviousness as well as commercial applicability. Generally, the term of a new patent is 20 years from the date at which the application for the patent was filed.

Solutions to breaking the roadblocks in biobanking public–private partnerships (Box 4)

Box 4 Main bottlenecks in practice and proposed solutions

Contract, ethics, and regulations

Heterogeneity of the contract form according to the different partners

– Use a standard and flexible contract form with the possibility of rapid amendments

– Contract and material transfer agreements that are readable in different languages and approved by both parties

– Better reactivity and willingness of TTO and/or legal offices

– Perfect knowledge of specific regulations for import–export of human biological products

Difficulties in the intellectual property perimeter assessment

– Copyright and patent possibilities are part of the contract

Cost evaluation of biological samples, associated data, and biobank infrastructure

– Improve the cost assessment according to international standards

Management and specimens

Long turnaround time for release of samples to the private partner

– Display delay times according to the request when setting up the contract

Specific requests made by the private partner

– Knowledge of the hazard status (HIV, Hepatitis, B and C serological status)

– Availability to different types and origins of specimen from the same cohort of patients

– Availability of associated expertises

– Follow-up of samples after delivery

Instability of the public biobank economic development

– Establishment of a long duration contract with private partners and customers retention/systematic customer development with key customers

Contract, ethics, and regulations

– Better assessment of cost recovery according to quality and relevance of biological and clinical data and annotations associated with samples and availability of associates expertise

Dissemination of information

Low levels of recognition of this area by the public

– Provide better dissemination through the media and patient' association mobilization (website, newsletter, meetings, etc.)

– Availability of informed consent readable in different languages

For the needs of patients, it is necessary to lift the constraints described above with regard to the PPPs in the biobanking field. A real paradox still exists regarding the fact that biobank managers complain about the underuse of collected samples that accumulate in their freezers (usually due to a lack of requests by researchers) and that the claim by industrial partners of the need of samples for biomarker validation (saying that these bioresources are usually inaccessible from the public biobanks) [18]. Many key points can contribute to overcome these misunderstandings, such as the recognition of a biobank as an active actor in the development of a scientific project conducted in collaboration with industry and the identification of a biobank in the project using their bioresources [19]. The scientific partnerships established between a biobank and industry will become stronger when the biobank provides solid parameters of evaluation and indicators. These indicators ensure the quality of the structure working with industry and they can be easily set up to address objective and quantifiable criteria that enhance the visibility of the private partners [9, 10]. The establishment of different levels of excellence for these structures can be done by external and independent evaluation, which may lead to public reports, accreditation, and/or certification [20]. The potential of the biobanks is enhanced when they work in a network with a focus on a scientific or medical theme. Moreover, the accessibility of industry to samples is easier, more rapid, and more efficient if these samples appear in well organized catalogues that are visible on a website [21].

It is of major importance to better mobilize public opinion, e.g., through patients' associations or diffusion in the media, in supporting the understanding and the usefulness of biobanks for the private research objectives. Informed consent to obtain samples is quite a problematic issue in general and depends on each countries' laws. So, we believe that currently it is certainly difficult to get a consensus in all countries on how to obtain signed consent that allows all types of research projects. Thus, specific consent can be obtained in case of a prospective study setup with industry, using samples stored in a biobank. In this latter case, the principal investigator of the project sets up the design of the study before the samples are taken from the patients. Specific consent cannot be obtained for a retrospective study that used samples stored for several years in the biobank, for example. In this latter situation, a "broad" signed consent is usually obtained to perform the research projects, including projects with private companies. More specifically, a sentence can be included in the consent form saying that part of the samples stored in the biobank could be used for a research project performed in collaboration with a private partner. This has been done in some institutions (Hospital-Integrated Tumor Biobank, Pasteur Hospital, Nice, France; www.biobank06.com). Better dissemination of information to the general public should promote the benefit of collaborating with industrial partners, on a fair and transparent basis [22–24]

Conclusion

Institutional PPP enable public health services to reap great benefit, when introduced as a complement to the traditional public service provisions for a defined set of services and goals, although one of the main challenges remains in changing the cultural habits [25, 26]. Fair PPP in biobanking are critical for both private and academic partners. Indeed, for an academic biobank to be competitive, it is very important to demonstrate efficiency, in particular when comparing with new private or commercial biobanks. PPP can be conceived as a way of renovating public biobank missions occurring through the involvement of private providers without loosing public sector control. Moreover, the sustainability of public biobanks, particularly when competing with commercial biobanks, depends on their capacity to get more funding and grants [27, 28]. The establishment of PPP may help biobanks to set up a stable business model and to better organize and anticipate their financial future [28].

All PPP have to be established keeping in mind clear and focused goals, so that the relationship between the public sector authority and the company could be regulated by service agreements specifying targets of activity, the corresponding fees and revenues, and, consequently, the return on investment. This arrangement could make purchasing a potential key steering tool. Inadequate funding, inadequate personnel and facilities, and absence of dedicated database software are also important roadblocks in collaboration with a private partner [29].

We believe that it is now necessary to reinforce and extend the scope of biobanks to include PPP. We propose that, based on the peer review process, the public sector should support biobanking infrastructures by sharing with industry the costs, risks, and knowledge. The European "Biobanking and Biomolecular Research Infrastructure" has paved the way to such a shift in policy. The success of projects such as the US Critical Path Initiative and the European Innovative Medical Initiative will largely rely on improvements in biobanking and on the concrete development of this new paradigm. Indeed, by engaging in fair relationships with biobanks, drug and

diagnostic companies would be more effective in building a knowledgeable community of clinicians and research scientists who share the same objectives.

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